Application No. 09/830,191
RCE/Amendment Dated Dec. 4, 2003
Reply to Final Office Action of June 4, 2003

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

10.(Currently Amended) Coated particles based on granulated microcrystals of ibuprofen, its isomers and its pharmaceutically acceptable salts, wherein they have a coating consisting of a mixture ~~comprising~~ consisting of:

A) from 5 to 50% by weight, ~~preferably from 10 to 30% by weight,~~ of ethyl cellulose, based on the ibuprofen,

B) from 10 to 60% by weight, ~~preferably from 15 to 50% by weight,~~ of hydroxypropyl methyl cellulose, based on the ethyl cellulose, ~~and~~

C) from 0.1 to 40% by weight, ~~preferably from 3 to 25% by weight,~~ of silica with antistatic and permeabilizing properties, based on the ethyl cellulose, and

D) from 0 to 50% by weight of an agent favoring the solubilization of the ibuprofen, based on the ibuprofen, said agent being selected from the group comprising mannitol, starch, pharmaceutically acceptable self-emulsifying bases, polyvinylpyrrolidones, stearic macrogol glycerides, alkali metal salts of organic origin, surfactants and mixtures thereof,

whereby said coating - of which at least one of the constituents can be used for the granulation of the ibuprofen microcrystals to produce said particles – allows the masking of the unpleasant taste of the ibuprofen, the significantly ~~reducing~~ reduction of its irritant effect on the throat after swallowing, and the release of 80% of ~~releasing~~ the ibuprofen ~~substantially immediately when the particles are placed in an aqueous medium~~ in 30 minutes in 900 ml of a buffer solution of pH 7.2, using a type 4 apparatus described in USP XXIII p. 1794.

11. (Currently Amended) Particles according to claim 10, having a coating consisting of a mixture ~~comprising~~ consisting of

A) from 10 to 30% by weight, of ethyl cellulose, based on the ibuprofen,

B) from 15 to 50% by weight, of hydroxypropyl methyl cellulose, based on the ethyl

cellulose, ~~and~~

C) from 3 to 25% by weight, of silica with antistatic and permeabilizing properties, based on the ethyl cellulose, and

D) from 0 to 35% by weight of an agent favoring the solubilization of the ibuprofen, based on the ibuprofen.

12. (Original) Particles according to Claim 10, wherein the silica with antistatic and permeabilizing properties (C) is precipitated silica.

13. (Cancelled)

14.(Original) Particles according to Claim 10, wherein the size distribution of the particles is such that at least 80% of the particles are between 100 and 500 μm and less than 15% of the particles are smaller than 100 μm.

15. (Cancelled)

16. (Currently Amended) Particles according to claim ~~15~~ 10, wherein in a buffer solution of pH 7.2, 80% of the ibuprofen is released in 15 minutes.

17. (Currently Amended) Process for the preparation of coated particles based on granulated microcrystals of ibuprofen, its isomers and its pharmaceutically acceptable salts, wherein it comprises, ~~simultaneously or~~ successively, phases consisting in granulating the ibuprofen microcrystals and coating them with a mixture ~~comprising~~ consisting of:

A) 5 to 50% by weight, ~~preferably 10 to 30% by weight,~~ of ethyl cellulose, based on the ibuprofen,

B) 10 to 60% by weight, ~~preferably 15 to 50% by weight,~~ of hydroxypropyl methyl cellulose, based on the ethyl cellulose, and

C) 0.1 to 40% by weight, ~~preferably 3 to 25% by weight,~~ of silica with antistatic and permeabilizing properties, based on the ethyl cellulose; and

D) 0 to 50% by weight based on ibuprofen of an agent favouring the solubilization of the ibuprofen, said agent being selected from the group comprising mannitol, starch, pharmaceutically acceptable self-emulsifying bases, polyvinylpyrrolidones, stearic macrogol glycerides, alkali metal salts of organic origin, surfactants and mixtures thereof.

at least one of the constituents of the mixture used for the coating can be used for the granulation of the ibuprofen microcrystals.

18. (Currently Amended) Process according to claim 17, wherein the mixture ~~comprises~~ consists of:

A) 10 to 30% by weight of ethyl cellulose, based on the ibuprofen,

B) 15 to 50% by weight of hydroxypropyl methyl cellulose, based on the ethyl cellulose, ~~and~~

C) 3 to 25% by weight of silica with antistatic and permeabilizing properties, based on the ethyl cellulose; and

D) 0 to 35% by weight based on ibuprofen of the agent favouring the solubilization of the ibuprofen.

19. (Cancelled).

20.(Currently Amended) Process according to Claim ~~19~~ 17, wherein it is carried out in a fluidized bed apparatus with an aqueous-alcoholic dispersion under conditions such that the temperature of the ibuprofen is always below 45°C.

21. (Original) Process according to Claim 20, wherein it is carried out in a fluidized bed apparatus with an aqueous-alcoholic dispersion under conditions such that the temperature of the ibuprofen is always below 30°C.

22. (Cancelled).